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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	15

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/610,134	Kay And Larche
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *May 18, 2001*

2a) ☐ This action is **FINAL.** 2b) X This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-12 and 15-31* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) X Claims *1-12 and 15-31* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) X Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) X All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4. Interview Summary (PTO-413) Paper No(s). _____
5. Notice of Informal Patent Application (PTO-152)
6. Other: _____

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, 12 and 15 drawn to a method of desensitizing a patient to a polypeptide allergen, classified in class 424, subclass 184.1,

II. Claims 8-11, 15-16, 24 and 26, drawn to a composition comprising one or more peptides derived from a polypeptide allergen or pharmaceutical composition thereof, classified in Class 530, subclass 300, and Class 514, subclasses 12-14,

III. Claims 17-23 and 27, drawn to a method of selecting a peptide for use as an immunotherapeutic agent for desensitizing a patient to a polypeptide allergen, classified in class 435, subclass 7.2,

IV. Claim 25, drawn to a database of peptides, classified in Class 707, subclass 100,

V. Claims 28-31, drawn to a method of determining an initial dose of an immunotherapeutic peptide for desensitizing a patient to a polypeptide allergen, classified in Class 424, subclass 9.2,

Note: The inventions of Claim 15 will be examined only to the extent of the elected invention.

2. The inventions are distinct, each from the other because:

3. Groups IV and II are of different statutory classes with the former being drawn to a database of peptides and the latter to a composition comprising one or more of a plurality of peptides derived from a polypeptide allergen or pharmaceutical composition. Therefore Groups IV and II are patentably distinct.

4. Groups II and Groups I/V are related as a product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the composition comprising a plurality of peptides derived from a polypeptide allergen could be used in immunoassays to determine the allergic states of patients

5. Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the peptides can be made by eluting the peptides from cells expressing MHC Class II in a patient undergoing an allergic

reaction.

6. Groups I, III and V are unique methods. They differ with respect to endpoints and method steps. A method of desensitizing a patient to a polypeptide allergen, a method of selecting a peptide for use as an immunotherapeutic agent for desensitizing a patient, and a method of determining an initial dose of an immunotherapeutic peptide for desensitizing a patient to a polypeptide allergen, represent patentably distinct subject matter.

7 Because Inventions I-V are distinct for the reasons given above, and they have acquired a separate status in the art because the searches of the non patent literature are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to the following patentably distinct species of the claimed Invention.

9. If Group I-V is elected, the applicant is further required under 35 U.S.C. 121 to elect a **specific Class II allele**, such as one recited in claim 4 or 23,

10. If Group I or V is elected, the applicant is further required to elect a **specific peptide allergen**, such as one recited in claim 6,

11. If Group II or IV is elected, the applicant is further required to elect a **specific genus of peptides**, such as a genus of peptides all of which are derived from one allergen such as those recited in claim 6.

12. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by [illegible] claims are added after the election applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. Claims 1-12 and 15-31 are generic.

16. The species are distinct each from the other for the following reasons:

A) Each class II molecule differs biochemically, has a distinct structure and binds a distinct set of peptide antigens.

B) each peptide allergen has distinct structures and encode distinct products.

C) each genus of peptides differ based on the criteria defining the genus.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. A telephone call to request an oral election was not made due to the complexity of the restriction and the requirement to comply with sequence rules.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service Please limit the use of this dedicated Fax number to

Papers **other than an election**, related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette. 1096 OG 30 (November 15. 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
September 10, 2001

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ART UNIT ~~182~~ 1647